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| 09/609,146      | 06/30/2000  | James A. Bonini      | 60794-B/JPW/KRD     | 2958             |

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EXAMINER

O HARA, EILEEN B

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 01/29/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/609,146

Applicant(s)

BONINI ET AL.

Examiner

Eileen B. O'Hara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 235-251, 254-263, 266-271 and 276-281 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 235-251, 254-263, 266-271 and 276-281 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

1. Claims 235-251, 254-263, 266-271 and 276-281 are pending in the instant application. Claims 235-237, 243-245, 249-251, 254, 258-259, 266-268 and 276-281 have been amended and claims 252, 253, 264, 265 and 272-275 have been canceled as requested by Applicant in Paper Number 14, filed November 4, 2002.

#### ***Priority***

2. Applicants' amendment to the specification to update the priority is acknowledged.

#### ***Withdrawn Rejections***

3. The rejections of claims under 112 § 1 are withdrawn in view of Applicants' amendment.

#### ***Specification***

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 235-251, 254-263, 266-271 and 276-281 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 235-251, 254-263, 266-271 and 276-281 are vague and indefinite because independent claims 235, 243, 249, 254 and 266 encompass a process involving competitive binding for identifying a chemical compound which specifically binds to a mammalian SNORF72 receptor or is an antagonist, by contacting cells with both a chemical compound and a second chemical compound known to bind to the receptor or known to be an agonist, and separately contacting cells with only the second chemical compound known to bind to the receptor, and comparing the amount of binding of the second chemical compound under the two conditions. The claims are indefinite because it is not clear what chemical compounds were known and were not known to bind to the receptor, and therefore the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The effective filing date for the amino acid sequence of SEQ ID NO: 4 is April 25, 2000, because that protein was first disclosed in parent application 09/588,099, and the effective filing date for the amino acid sequence of SEQ ID NO: 25 is the filing date of the instant application, June 30, 2000, since the protein was not disclosed in any parent application.

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6. Claims 235, 238-244, 246-249, 254-256, 260-266, 269-276 and 279 are rejected under 35 U.S.C. 102(e) as being anticipated by Elshourbagy et al., U.S. Patent No. 6,461,836, effective filing date Nov. 5, 1999.

Claims 235, 238-244, 246-249, 254-256, 260-266, 269-276 and 279 encompass a process involving competitive binding for identifying a chemical compound which specifically binds to a mammalian SNORF72 receptor that has above 75% amino acid identity to the amino acid sequence of SEQ ID NO: 4, or is an antagonist, by contacting cells with both a chemical compound and a second chemical compound known to bind to the receptor or known to be an agonist, and separately contacting cells with only the second chemical compound known to bind to the receptor, and comparing the amount of binding of the second chemical compound under the two conditions or the activation of a second messenger system which may be chloride channel activation, intracellular calcium levels, and wherein the cells may be insect, mammalian or COS cells. Also encompassed is a process for preparing a composition which comprises a chemical compound identified by the screening methods by admixing a pharmaceutically acceptable carrier.

Elshourbagy et al. disclose a protein identified as human AxOR34 (SEQ ID NO: 2) that is 98.9% identical to the amino acid sequence of SEQ ID NO: 4 and 79% identical to SEQ ID NO: 25 of the instant application (see attached sequence alignments). Elshourbagy et al. teach that AxOR34 is a receptor that binds neuromedin U ligands, and that the receptor can be used to screen for compounds that bind to it using competitive binding assays, wherein binding, inhibition or activation can be measured by second messenger systems including detection of calcium or other ions (see title, abstract, column 3, lines 20-61, column 8, lines 58-65, column

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12, line 21 to column 15, line 40, examples 1-8), and cells such as insect cells and COS cells that can be used to express the receptor (column 8, lines 27-33). Elshourbagy et al. also teaches that agonists and antagonists to the receptor are encompassed in the invention (column 15, lines 41-44, column 16, lines 9-53), and that polypeptides of the invention can be in a formulation comprising a carrier for administration (column 11, line 47 to column 12, line 20). Therefore, Elshourbagy et al. anticipates the claims.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7.1 Claims 236, 244, 250, 257, 258, 267, 277 and 280 are rejected under 35 U.S.C. 103(a) as being unpatentable over Behan et al., WO 00/22131, April 20, 2000 (cited by Applicants in IDS

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Paper No. 5), in view of Elshourbagy et al., U.S. Patent No. 6,461,836, and further in view of Conklin et al., U.S. Patent No. 6,383,761, filing date July 27, 1998.

Claims 236, 244, 250, 258, 267, 277 and 280 encompass a process involving competitive binding for identifying a chemical compound which specifically binds to a human SNORF72 which as an amino acid sequence identical to the amino acid sequence of SEQ ID NO: 4, or is an antagonist, by contacting cells with both a chemical compound and a second chemical compound known to bind to the receptor or known to be an agonist, and separately contacting cells with only the second chemical compound known to bind to the receptor, and comparing the amount of binding of the second chemical compound under the two conditions or the activation of a second messenger system which may be chloride channel activation, intracellular calcium levels, or inositol phosphate levels. Also encompassed is a process for preparing a composition which comprises a chemical compound identified by the screening methods by admixing a pharmaceutically acceptable carrier.

The teachings of Elshourbagy et al. are summarized as above. Elshourbagy et al. does not disclose that detection of inositol phosphate could be used in the screening method.

Behan et al. discloses a human G-protein coupled receptor (see pages 86-87) which is 100% identical to the polypeptide of SEQ ID NO: 4 of the present application (see Previous Office Action, Paper No. 13, page 8. Behan et al. did not teach what the ligand for the receptor was and did not appreciate that their polypeptide was a receptor for neuromedin U neuropeptides.

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Conklin et al. teach that diacylglycerol activates certain protein kinase Cs (PKCs) and certain inositol phosphates stimulate the mobilization of calcium from intracellular stores (column 2, lines 9-12).

Elshourbagy et al. disclose a protein identified as human AxOR34 (SEQ ID NO: 2) that is 98.9% identical to the amino acid sequence of SEQ ID NO: 4, having four mismatches out of 415 amino acids. The specification teaches that stimulation of the protein of SEQ ID NO: 4 results in intracellular calcium release (Figures 6-7), and therefore level of inositol phosphate, which controls calcium release as taught by Conklin et al., could also be assayed. It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to use the receptor of Behan et al. in methods of screening for compounds that bind or are antagonists or agonists for the receptor and that utilize second messenger systems as taught by Elshourbagy et al. or as taught by Conklin et al., and to make compositions of such identified compounds as taught by Elshourbagy et al. The skilled artisan would be motivated to do so because they would immediately have recognized that Behan et al.'s receptor is a variant of the receptor of Elshourbagy et al., and would wish to compare the activities between the two receptors to determine if the amino acid changes result in different activities. There would have been a reasonable expectation of success, since the methods of screening GPCRs had been utilized extensively.

### ***Conclusion***

7. No claim is allowed.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312.

The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner

  
**LORRAINE SPECTOR**  
**PRIMARY EXAMINER**